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| 09/003,047 | 01/05/1998 | ALBERT J J VAN OYEN | 261922003302 | 8520 |

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EXAMINER

NELSON, AMY J

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/14/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/003,047

Applicant(s)

VAN OUYEN ET AL.

Examiner

Amy Nelson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 5/16/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27,28,42,48,51,54-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,27,28,42,48,51 and 54-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 35.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The Information Disclosure Statement originally filed 4/9/98, and resubmitted on 5/16/03, has been considered and a copy is submitted herewith.
2. The drawings filed 5/16/03 have been approved by the Draftsperson.
3. The references on the Notice of References Cited were inadvertently not mailed with the Official action mailed 1/10/03, and are submitted herewith.

Claim Objections

4. Claims 56 and 58 are objected to because of the following informalities:

At Claim 56, line 1, the phrase "transformed, transgenic plant" is redundant. It is recommended that the phrase be changed to --transgenic plant--.

At Claim 58, line 1, the phrase "transformed, transgenic plant" is redundant. It is recommended that the phrase be changed to --transgenic plant--.

Claim Rejections - 35 USC § 112

Claims 1, 27, 28, 42, 48, 51, and 54-58 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 1/10/03. Applicant's arguments filed 5/16/03 have been fully considered but they are not persuasive.

Applicant asserts that the specification lists examples of endo-glucanases at page 6 of the specification (response, p. 6, second paragraph). However, the cited portion of the specification describes the enzymes, not the nucleic acids required for the claimed vectors, methods and transgenic plants.

Applicant argues that nucleic acid sequences encoding microbial endo-glucanases were well known in the art at the time the application was filed, and Applicant submits Appendix B as evidence of prior art publications describing microbial endo-glucanases (response, p. 6, second paragraph). Applicant is invited to submit the references for consideration.

Applicant's further assert that the Baird reference cited by the examiner in the Official action mailed 1/10/03 also teaches microbial nucleic acid sequences encoding endo-glucanase (response, p. 6, second paragraph). Hence, Applicant urges that nucleic acid sequences encoding microbial endo-glucanases were well known in the art at the time of filing, and that the prior art adequately describes the claimed genus of nucleic acid sequences required for Applicant's claimed invention (response, paragraph bridging p. 6-7). However, even considering the references in Appendix B and the Baird reference, the prior art nucleic acid sequences are at best descriptive of the genus of bacterial nucleic acids encoding endo-glucanases, and not all bacterial, fungal, protozoa and viral nucleic acids encoding endo-glucanases as broadly claimed. Further, it is not clear that there is adequate written description for each of 1,3-B glucanase nucleic acids and 1,4-B glucanase nucleic acids as per claims 27 and 28. Further, it is submitted that Applicant has not described plants comprising said nucleic acids.

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5. Claims 1, 27, 28, 42, 48, 51, and 54-58 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as set forth in the Official action mailed 1/10/03. Applicant's arguments filed 5/16/03 have been fully considered but they are not persuasive.

Applicant asserts that endo-glucanases are taught at page 6 of the specification (response, p. 7, last paragraph). However, as discussed above, the specification only teaches the enzymes, not the nucleic acids required for the claimed invention.

Applicant further asserts that the regulatory elements and leader sequences required for the claimed invention are disclosed at page 9-10 of the specification (response, paragraph bridging p. 7-8). However, the disclosed leader sequences target particular cellular organelles, not the polysaccharide/saccharide component contained within a cellular compartment or organelle. Hence, Applicant has not provided guidance for the targeting or leader sequences as claimed.

Further, Applicant urges that plants and methods of transformation were well known in the art, and that plants could be selected based on the desired end result. Also, methods of assessing endo-glucanase activity were well known in the art. Applicant asserts that the examples illustrate the operation of the invention, and the object is merely to modify polysaccharide/saccharide composition of plants or plant organs (response, p. 8, first and second paragraphs). Examiner does not dispute that plants and methods for plant transformation were well known in the art at the time of applicant's invention. However, methods of making directed

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alterations to plant phenotype were highly unpredictable for the reasons set forth in the previous office action. Contrary to Applicant's assertion, the examples are not directed to a method of modifying polysaccharide or saccharide composition in plants by transformation with microbial endo-glucanase nucleic acids, nor to transgenic plants thereby produced.

Applicant refers to the Pen Declaration filed 8/1/00 stating that identification, characterization and testing of microbial endo-glucanase nucleic acids could be routinely done by one of skill in the art. Applicant also refers to the Baird reference of the prior art teaching of two *Bacillus* nucleic acids encoding endo-glucanase (response, paragraph bridging p. 8-9). Applicant appears to be referring to paragraphs 2 and 3 of the Pen Declaration which state that new microbial endo-glucanase nucleic acids could be readily identified by sequence homology and would share the common property or physical characteristic of being able to express glucanase under the correct conditions. However, the Pen Declaration is merely a statement of opinion. Examiner maintains, for the reasons stated in the previous office action, that Applicant provides no specific guidance with respect to probe or oligo sequences, hybridization and wash conditions, or PCR reaction conditions to allow one of skill in the art to selectively isolate sequences encoding endo-glucanase from other nucleic acids including nucleic acids encoding exo-glucanases, for example. In the absence of such guidance, undue trial and error experimentation would be required to screen through the myriad of genomic or cDNA clones from any and all microbial organisms to identify the claimed nucleic acids. Knowing the function of the gene product does not aid in isolation of the nucleic acids.

Applicant argues that the Harpster reference is not concerned with polynucleotides from a microbial source and is not relevant to the claimed invention. Also, although Harpster did not

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achieve depolymerization of the particular glycan xyloglucan as intended, the non-xyloglucan matrix glycans were lost from the soluble extract of the transgenic plants, and hence the polysaccharide/saccharide composition of the transgenic plants was modified (response, p. 9, last paragraph). Examiner responds that the Harpster reference is indeed relevant because it is directed to expression of an endo-glucanase nucleic acid in transgenic plants. Although the nucleic acid is from plants, the unpredictable phenotypic effects are still meaningful. Further, if overexpression of a plant nucleic acid causes such unpredictability in a closely related plant host organism, one would only expect even greater unpredictability upon expression of a distantly related microbial nucleic acid. The Harpster reference serves to demonstrate that one can not make targeted, predictable phenotypic effects in plants by transformation with an endo-glucanase nucleic acid. Even if unexpected effects on polysaccharide/saccharide content did occur, it is unclear how Applicant can use this to demonstrate enablement of the claimed invention. Simply being able to manipulate polysaccharides or saccharides in plants is not enough; Applicant must be able to demonstrate predictable obtention of transgenic plants with desired phenotypic changes. In the instant specification, Applicant has failed to teach how to produce targeted, desired phenotypic alterations in polysaccharides or saccharides in plants, and how to use the plants so obtained. Short of such detailed guidance, Applicant has only provided an invitation to experiment.

Similarly, Applicant asserts that the Carvalho reference also teaches transformation of plants with a plant nucleic acid encoding endo-glucanase and hence is not relevant to the instant invention. Further, whereas it would be expected that Carvalho would find evidence of gene

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silencing by transformation with the endogenous gene, such effects would not be expected by transformation with microbial nucleic acids as claimed herein (response, p. 10, first paragraph). Examiner maintains that the teachings of Carvalho, although plant nucleic acids, are relevant for the reasons discussed above. Also, gene silencing may occur even though the nucleic acid is heterologous to the host organism, provided there is sufficient sequence identity. Hence, it is one of the factors that adds to unpredictability in plant transformation, and there is no guarantee that any transformation event is free from the problems of gene silencing. Therefore, the rejection is maintained.

6. Claims 1, 27, 28, 42, 48, 51, and 55-58 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 1/10/03. Applicant's arguments filed 5/16/03 have been fully considered but they are not persuasive.

At Claim 1, line 1, the phrase "modifying the polysaccharide/saccharide composition" is indefinite. Similarly, at Claim 58, lines 2-3, the phrase "endo-glucanase modified polysaccharide/saccharide material" is indefinite. Applicant asserts that the claim is directed to a method of modifying polysaccharide/saccharide composition by expression of a microbial endo-glucanase. Hence, the polysaccharide/saccharide content of the plant or plant organ is altered (response, p. 11, last paragraph). However, Applicant fails to address the issue. The phrase is unclear because it is not known in what way polysaccharide composition or saccharide composition is increased, *i.e.* is the level of one or both increased, is the level of one or both

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decreased, is the proportion of a particular polysaccharide compound or a particular saccharide changed with respect to others, *etc.*

At Claim 1, line 12, "the polysaccharide/saccharide material" is indefinite. Applicant urges that the leader sequence targets the expressed endo-glucanase to polysaccharide/saccharide material in a desired cellular compartment or organelle (response, p. 12, first paragraph). However, as stated in the previous office action, it unclear what components of cellular compartments or organelles are intended. Polysaccharides and saccharides are omnipresent in the cell, and hence it is unclear how and what components of the cell or of particular organelles are targeted. Also, examiner is not aware of leader sequences that target within an organelle or to a particular type of macromolecule, and hence it is not clear what is intended by Applicant.

Claim Rejections - 35 USC § 103

7. Claims 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornelissen *et al.* (U.S. Patent 6,066,491; effective filing date 1/29/91) or Cornelissen *et al.* (EP 440,304; 8/7/91), either in view of Baird *et al.* (J. Bacteriol. 172: 1576-1586, 1990). This rejection is repeated for the reasons of record as set forth in the last Official action mailed 1/10/03. Applicant's arguments filed 5/16/03 have been fully considered but they are not persuasive.

Applicant asserts that the instant application claims priority to EPO 90202438.4, filed September 13, 1990, which antedates the Cornelissen reference (response, p. 13, third paragraph). Examiner thanks Applicant for pointing to the claim to foreign priority in the oath. However, the claim to foreign priority is problematic for several reasons. First of all, the oath recites "EPO 90202434.8" which appears to be the incorrect EP patent number. Secondly, the

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first line of the specification recites that the instant application is a continuation of Serial No. 08/253,575 filed 6/3/94, which is a continuation of 07/859,422 filed 6/12/92. Hence, the filing date of the foreign application, 9/13/90, is more than a year before the earliest U.S. filing date. Lastly, Examiner was unable to obtain the EP patent from the parent application. Applicant is kindly requested to provide a copy of the foreign patent (and translation if necessary) so that Examiner can determine if the invention was adequately described in the European patent.

Applicant further asserts that the Baird reference does not teach or suggest expression of microbial endo-glucanase nucleic acids in transgenic plants (response, p. 13, fourth paragraph). However, as the instant rejection is an obviousness rejection, Baird need not teach all of the claim limitations. It is the combination of the teachings of Cornelissen and Baird that renders the claimed invention obvious.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication should be directed to Amy Nelson at (703) 306-3218. The examiner can normally be reached Monday-Thursday from 7:00 am to 5:30 pm.

The fax number for TC 1600 is (703) 872-9306 (before final) or (703) 872-9307 (after final).

Any inquiry of a general nature, relating to the status of this application or if a paper has not been received, should be directed to TC 1600 Customer Service at (703) 308-0198.

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**